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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.         | CONFIRMATION NO. |
|---|-------------|----------------------|-----------------------------|------------------|
| 10/722,060  | 11/25/2003  | Donal Coveney        | TOMK-0001<br>(122359.00003) | 4165             |
| 7590  | 01/10/2006  |                      | EXAMINER                    | OH, TAYLOR V     |
| T. Ling Chwang<br>Suite 600<br>2435 N. Central Expressway<br>Richardson, TX 75080 |             |                      | ART UNIT                    | PAPER NUMBER     |
|   |             |                      | 1625                        |                  |

DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                     |                         |  |
|------------------------------|-------------------------------------|-------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b>              | <b>Applicant(s)</b>     |  |
|                              | 10/722,060                          | COVENEY ET AL.          |  |
|                              | <b>Examiner</b><br>Taylor Victor Oh | <b>Art Unit</b><br>1625 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 17 October 2005.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-4,7-9 and 11-15 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) 1-4,7-9 and 12-14 is/are allowed.  
 6) Claim(s) 11 is/are rejected.  
 7) Claim(s) 15 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
     1. Certified copies of the priority documents have been received.  
     2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
     3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/17/05 has been entered.

**The Status of Claims:**

Claims 1-4, 7-9, and 11-15 are pending.

Claim 11 has been rejected.

Claim 15 has been objected.

Claims 1-4, 7-9, 12-14 are allowable.

**DETAILED ACTION**

**Priority**

1. None.

**Drawings**

2. None.

**Claim Objections**

Claim 15 is objected to because of the following informalities:

In Claim 15, the Claim is objected to under 37 CFR 1.75(c) as being in improper form because of its being dependent on a multiple dependent claim 14 See MPEP § 608.01(n). Accordingly, the claim 15 is not been further treated on the merits.

***Claim Rejections - 35 USC § 103***

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1625

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

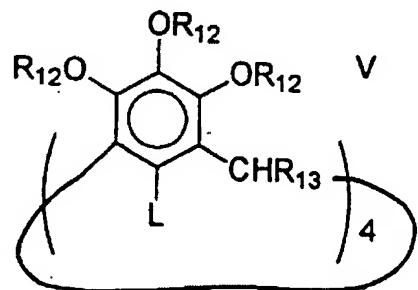
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

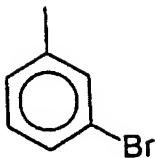
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Harris (WO 95/19974) in view of Aldrich (page 811, 1999).

Harris teaches cyclic tetrameric pyrogallol-aldehyde derivatives of the following compounds (see page 8, lines 14-36) :



wherein  $\text{R}_{12}$  is H or  $\text{CH}_2\text{CO}_2\text{M}$  ( $\text{M}$  is metal ion) (see page 7, line 31);  $\text{L}$  is halogen, H, or other electron withdrawing group; and  $\text{R}_{13}$  is



The invention further provides pharmaceutical compositions comprising a pharmaceutically effective amount of any of the above defined compounds, either singly or in combination. The invention also provides use of any of the above defined compounds, either singly or in combination, in the preparation of a medicament for the treatment of bacterial infection, fungal infection or viral infection, particularly HIV-1, HIV-2 or SIV infection. The invention also provides a method of medical treatment comprising administering a therapeutically effective amount of any of the above defined compounds to a patient, either singly or in combination.  
(see page 13 , lines 11-20).

Furthermore, Harris discloses the preparation of pyrogallol-aldehyde cyclic tetramers and derivatives (see page 122, examples 184 and 185) by the reaction of m-bromobenzaldehyde and pyrogallol (see page 49, example 181) in 1 : 4 with HCl under nitrogen (see, page 45, example 163 , lines 30-34), and the reaction mixture is further etherified with ethyl bromoacetate and potassium carbonate in acetone (see, page 46, example 165 , lines 5-9), and then further treated with potassium hydroxide in ethanol in order to obtain the desired product(see, page 45, example 169 , lines 30-35).

However, the instant invention differs from the prior art in that the claimed R<sub>2</sub> group is para-fluorobenzene instead of the meta-bromobenzene group.

Even so, the substituent on the benzene ring in the prior art and the instant invention is belonged to the halogen family in which the bromine and the fluorine have a similar reactivity between them; furthermore, they are related to each other with respect to the positional isomers. It is obvious to the skilled artisan in the art to be motivated to substitute the known fluoride group to the para-position instead of the meta position of the benzene group in the absence of an unexpected result.

Harris expressly teaches the method of producing the cyclic tetrameric pyrogallol-aldehyde derivatives having the meta-bromobenzene group as the R<sub>2</sub> group by reaction of m-bromobenzaldehyde and pyrogallol (see page 49, example 181). The reactivity between the bromine and the fluorine is similar to each other because of the same periodic family; also, they are in a positional isomer-relationship. Moreover, the p-fluorobenzaldehyde is well-known compound in the art as shown in Aldrich (page 811, 1999). Therefore, if the skilled artisan in the art had desired to make the cyclic tetrameric pyrogallol-aldehyde derivatives having the para-fluorobenzene group as the R<sub>2</sub> group, it would have been obvious to the skilled artisan in the art to be motivated to use the Aldrich's p-fluorobenzaldehyde as the starting material in the Harry's process as an alternative because the skilled artisan in the art would expect such a modification to be successful as shown in the Harry process due to the equivalency of their reactivity between the bromine and the fluorine substituents.

Applicants' Argument

Applicants argue the following issues:

- a. The rejections under 35 USC 112 ,second, are unclear.
- b. The claimed compounds are partially alkylated as shown in the claims, whereas the Harris' compounds are fully alkylated or non-alkylated.

Applicants' arguments have been noted, but the arguments are not persuasive.

Regarding the first argument , the Examiner has agreed.

Regarding the second argument , the Examiner has noted applicants' argument.

All the claims 1-4, 7-9, 12-14 are directed to the compounds having different degrees of alkylation except claim 11. Therefore, the Harris prior art is still applicable to the rejection of claim 11 because it is written in such a way that the claimed process can be taken place either in a partial degree of alkylation or a full degree of alkylation.

In summary, Claims 1-4, 7-9, 12-14 are allowable except claim 11.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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*Mylaw V. Dr.*  
1/6/06